

PATENT COOPERATION TREATY

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NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C.20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 24 November 1999 (24.11.99)	
International application No. PCT/GB99/01434	Applicant's or agent's file reference PG3433/PCT
International filing date (day/month/year) 07 May 1999 (07.05.99)	Priority date (day/month/year) 09 May 1998 (09.05.98)
Applicant BONNEFOY, Jean-Yves, Marcel, Paul et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
19 October 1999 (19.10.99)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer S. Mafla Telephone No.: (41-22) 338.83.38
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INTERNATIONAL SEARCH REPORT.

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference PG3433/PCT	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/GB 99/ 01434	International filing date (day/month/year) 07/05/1999	(Earliest) Priority Date (day/month/year) 09/05/1998
Applicant GLAXO GROUP LIMITED et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.
☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☒ contained in the international application in written form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

ANTIBODIES TO CD23, DERIVATIVES THEREOF, AND THEIR THERAPEUTIC USES

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures.

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 C12N15/13 C07K16/28 A61K39/395 C12N15/62

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 C07K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	J. BONNEFOY ET AL.: "Production and characterization of a monoclonal antibody specific for the human lymphocyte low affinity receptor for IgE: CD23 is a low affinity receptor for IgE." THE JOURNAL OF IMMUNOLOGY, vol. 138, no. 9, 1 May 1987 (1987-05-01), pages 2970-2978, XP002113646 Baltimore, MD, USA abstract page 2973, right-hand column, line 4 - line 8	2,4,6,7
Y	---	11,12,18
Y	WO 96 12741 A (GLAXO GROUP LTD.) 2 May 1996 (1996-05-02) example 12 claims ---	11,12,18
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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

30 August 1999

Date of mailing of the international search report

09/09/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
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Authorized officer

Nooij, F

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	C. PLATER-ZYBERK ET AL.: "Marked amelioration of established collagen-induced arthritis by treatment with antibodies to CD23 in vivo." NATURE MEDICINE, vol. 1, no. 8, August 1995 (1995-08), pages 781-785, XP002113647 New York, NY, USA the whole document ---	1-19
A	L. FLORES-ROMO ET AL.: "Inhibition of an in vivo antigen-specific IgE response by antibodies to CD23." SCIENCE, vol. 261, no. 5124, 20 August 1993 (1993-08-20), pages 1038-1041, XP002113648 Washington, DC, USA the whole document ---	1-19
A	WO 93 02108 A (IDEC PHARMACEUTICALS) 4 February 1993 (1993-02-04) claims ---	4,5,11, 18
P,X	WO 98 37099 A (IDEC PHARMACEUTICALS CORP. & SEIKAGAKU CORP.) 27 August 1998 (1998-08-27) examples claims -----	2,4,11, 12,18

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No



PCT/GB 99/01434

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9612741	A	02-05-1996	AU 698158 B	22-10-1998
			AU 3843595 A	15-05-1996
			AU 3867995 A	15-05-1996
			BR 9509434 A	06-01-1998
			BR 9509498 A	23-12-1997
			CA 2203363 A	02-05-1996
			CA 2203364 A	02-05-1996
			CN 1171119 A	21-01-1998
			WO 9612742 A	02-05-1996
			EP 0788513 A	13-08-1997
			EP 0788514 A	13-08-1997
			FI 971756 A	24-04-1997
			HU 77572 A	29-06-1998
			JP 9511757 T	25-11-1997
			JP 10507460 T	21-07-1998
			NO 971902 A	24-04-1997
			ZA 9508947 A	31-07-1996
WO 9302108	A	04-02-1993	AP 307 A	31-01-1994
			AU 673499 B	14-11-1996
			AU 2425592 A	23-02-1993
			BG 98411 A	28-02-1995
			BR 9206313 A	11-04-1995
			CA 2114015 A	04-02-1993
			CZ 9400149 A	13-07-1994
			EP 0605442 A	13-07-1994
			FI 940336 A	10-03-1994
			HU 70272 A	28-09-1995
			HU 211881 B	28-12-1995
			JP 6509708 T	02-11-1994
			KR 137806 B	30-04-1998
			MX 9204374 A	01-03-1993
			NO 940219 A	25-03-1994
			NZ 243706 A	26-08-1994
			OA 9879 A	15-09-1994
			PT 100735 A	29-10-1993
			SK 8894 A	07-09-1994
			US 5658570 A	19-08-1997
			US 5756096 A	26-05-1998
			US 5750105 A	12-05-1998
			US 5681722 A	28-10-1997
			US 5693780 A	02-12-1997
WO 9837099	A	27-08-1998	AU 6146998 A	09-09-1998
			ZA 9801434 A	24-08-1998

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PG3433/PCT		FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB99/01434	International filing date (day/month/year) 07/05/1999	Priority date (day/month/year) 09/05/1998	
International Patent Classification (IPC) or national classification and IPC C12N15/13			
Applicant GLAXO GROUP LIMITED et al.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 19/10/1999		Date of completion of this report 28.07.2000	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer Paresce, D Telephone No. +49 89 2399 8995 	

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB99/01434

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-39 as originally filed

Claims, No.:

1-19 as originally filed

Drawings, sheets:

1/7-7/7 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB99/01434

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1, 3, 5, 8-10, 13-17
	No:	Claims	2, 4, 6-7, 11-12, 18-19
Inventive step (IS)	Yes:	Claims	1, 3, 5, 8-10, 13-17
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-19
	No:	Claims	

2. Citations and explanations

see separate sheet

Re l t m V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 1) The documents mentioned in this communication are numbered as in the search report, i.e. D1 corresponds to the first document of the search report.

- 2) **Novelty: Article 33(2) PCT**

The subject-matter of claims 2, 4, 6-7, 11-12, 18-19 is not considered new in the sense of Article 33(2) PCT for the following reasons:

D1 discloses the production and characterization of a monoclonal antibody, Mab 25, specific for the human lymphocyte low affinity receptor for the Fc fragment of IgE: CD 23. The affinity constant of Mab 25 is $K_a: 10^{10} \text{ M}^{-1}$ (p. 2973). D1 also discloses Fab fragments of Mab 25 and biotinylation of Mab 25 (p.2972). The IPEA considers Mab 25 described in D1 to fall under the scope of claims 2, 4, 6-7 of the present application.

D2 also describes anti-CD23 Mab 25 (see examples 10-12) as well as other binding agents to CD23. D2 describes the use of CD23 binding agents in the treatment or prophylaxis of various diseases. In particular, D2 discloses antibodies specific for CD23, fragments thereof, humanized antibodies, methods of use of said antibodies in human therapy, and in pharmaceutical compositions in combination with an immunomodulatory or anti-inflammatory agent (see claims). Therefore, the subject-matter of claims 2, 4, 6-7, 11-12, 18-19 is not considered new.

The subject-matter of claims 1, 3, 5, 8-10, 13-17 has not been made available to the public by any of the available prior art documents and can therefore be regarded as novel.

The subject-matter of claims 1, 3, 5, 8-10, 13-17 cannot be derived from the available prior art in an obvious manner and therefore complies with the requirements of Article 33(3) PCT.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB99/01434

VI: Certain documents cited

Certain published documents (Rule 70.10)

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO9837099	27.08.98	17.02.98	20.02.97



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : C12N 15/13, C07K 16/28, A61K 39/395, C12N 15/62	A1	(11) International Publication Number: WO 99/58679 (43) International Publication Date: 18 November 1999 (18.11.99)
(21) International Application Number: PCT/GB99/01434 (22) International Filing Date: 7 May 1999 (07.05.99) (30) Priority Data: 9809839.5 9 May 1998 (09.05.98) GB (71) Applicant (for all designated States except US): GLAXO GROUP LIMITED [GB/GB]; Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): BONNEFOY, Jean-Yves, Marcel, Paul [FR/FR]; Institut de Recherche Pierre Fabre, F-74164 Saint-Julien-en-Genevois Cedex (FR). CROWE, Scott, James [GB/GB]; Glaxo Wellcome plc, Gunnels Wood Road, Stevenage, Hertfordshire SG1 2NY (GB). ELLIS, Jonathan, Henry [GB/GB]; Glaxo Wellcome plc, Gunnels Wood Road, Stevenage, Hertfordshire SG1 2NY (GB). RAPSON, Nicholas, Timothy [GB/GB]; Glaxo Wellcome plc, Gunnels Wood Road, Stevenage, Hertfordshire SG1 2NY (GB). SHEARIN, Jean [US/US]; Glaxo Wellcome Inc., Five Moore Drive, Research Triangle Park, NC 27709 (US).		(74) Agent: STOTT, Michael, J.; Glaxo Wellcome plc, Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN (GB). (81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: ANTIBODIES TO CD23, DERIVATIVES THEREOF, AND THEIR THERAPEUTIC USES (57) Abstract <p>The invention relates to antibodies which bind to the CD23 (FCεRII) type II molecule particularly altered antibodies including antibodies which bind to the CD23 (FCεRII) type II molecule characterised by an affinity constant equal to or greater than $1 \times 10^9 \text{ Ka Mol}^{-1}$, the preparation of such antibodies, pharmaceutical compositions which contain such antibodies and their use in therapy particularly in the treatment of autoimmune and inflammatory disorders.</p>		

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